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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,687	02/11/2002	Feng-Jing Chen	6200-0004.20	9747

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THORPE NORTH & WESTERN, LLP.
8180 SOUTH 700 EAST, SUITE 200
P.O. BOX 1219
SANDY, UT 84070

EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,687	CHEN ET AL.	
	Examiner	Art Unit	
	Lakshmi S Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-145* is/are pending in the application.

4a) Of the above claim(s) *3,4,18-23,38,67-71,88-93,108 and 134-145* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-17,24-37,39-66,72-87,94-107 and 109-133* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/11/02;7/7/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of response to election requirement dated 9-17-04 and Information disclosure statements dated 2-11-02 and 7-07-03 is acknowledged.

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 9-17-04 is acknowledged. In response to the election of species, applicants elected Species 1 and stated that each and every claim of group I reads on the elected species i.e., a formulation wherein an active agent has a first fraction solubilized in a vehicle as indicated by Species 1. However, examiner notes that Species 1 only includes claims 1, 2, 5-17, 24-37, 39-66, 72-87, 94-107 and 109-133. Claims 3, 4, 18-23, 38, 67-71, 88-93 and 108 (of Group I) are withdrawn as being non-elected. Further, claims 134-145 of Group II are withdrawn as being non-elected. Accordingly, claims 3, 4, 18-23, 38, 67-71, 88-93, 108 and 134-145 are withdrawn as being non-elected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 5-17, 24-37, 39-47, 59-66, 72-87, 94-107, 109-114 and 126-133 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,589,513 to Magyar et al (Magyar)

Magyar teaches pharmaceutical compositions comprising two phases and a MAO inhibitor as an active agent (col. 4, lines 17-55). Magyar teaches the composition in the form of pellets, tablets, capsules, coated capsules etc (Col. 4, lines 56-61); and suggests adding auxiliary agents (that read on the instant additives of claim 25) such as fillers (col. 4, lines 65-68), binders, cellulose derivatives, Eudragit, lipophilic bases, granulating liquids etc (col. 5, lines 1-16) to the composition, which read on the instant stabilizers and suspending agents. The examples of Magyar specifically teach methocel, PVP, Carbopol, carbomer, etc. The composition of Magyar is prepared by dry granulation method (col. 6). Example 7 of Magyar particularly includes the components that are also exemplified in the instant specification. In col. 7, lines 16-30, Magyar teaches the preparation of the composition, wherein the MAO inhibitor, deprenyl, is dissolved as well as suspended in propylene glycol and Cremophor Magyar also teaches both crystalline and particulate states of the active agent (col. 11) and also teaches both slow and fast release profiles of the formulation (col. 8).

Magyar does not teach the exact percentages of first fraction and second fraction of the active agent, composition free of water–indispersible wax materials and also fails to teach the claimed dissolution parameters. However, Magyar teaches a pharmaceutical formulation for providing fast and immediate release rates having different release profiles and suggests the same excipients that are also used and claimed in the instant. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to optimize the amounts of the fractions dissolved or dispersed so as to achieve the desired dissolution parameters, depending on the active agent and other excipients employed

Claim1, 2, 5-8, 11, 24- 27, 29-33, 36, 37, 39-59, 72-78, 81, 94-97, 99-103, 106, 107 and 109-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,303,662 to Nagahama et al (Nagahama) or over GB 2098865 (GB).

Nagahama teaches microemulsions compositions containing highly oil soluble drugs, a highly polar oil, a low polar oil, a polyglycerol fatty acid ester (read on instant surfactant) and water-soluble polyhydric alcohol, and a method preparing the same. The lowly polar oils used for emulsification by Nagahama include oils and triglycerides (col. 2, lines 13-30). The oil soluble drugs of Nagahama are particulate in nature (col. 4, lines 9-14). The microemulsion preparations of Nagahama employ the same methods of preparation as in instant examples (col. 3, lines 63-col. 4, lines 9). While Nagahama fails to state that the active agent is partly suspended (dispersed) and partly dissolved in the vehicle, Nagahama employs the vehicles that are claimed and also employed in the instant examples and accordingly, the burden is shifted to applicants to show that the claimed limitation is not achieved by Nagahama. Further, Nagahama does not teach the claimed lipid regulating agents and the sex hormones. However, Nagahama teaches the compositions specifically for oil soluble active agent and for stabilizing the oil soluble drugs. Therefore it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare microemulsions of Nagahama with any known oil soluble agents including fenofibrate or estradiol, as claimed, with an expectation to achieve a stable emulsion preparation because Nagahama suggests that a combination of high and low polar oils as an oil for dissolution, together with an emulsifier improves the stability of the emulsion.

GB teaches a skin penetration pharmaceutical composition in the form of a microemulsion comprising an active agent that is relatively hard to penetrate through the skin, a

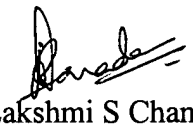
combination of an emulsifier and a co-emulsifier and a fatty alcohol or a mixture of water-soluble and water-insoluble non-ionic surfactants (page 2, lines 15-59). Among the excipients, GB teaches emulsifiers, co-emulsifiers, solvents, all of which are also described in the instant invention (page 3). GB teaches active agents such as tetracycline and tizanidine but not lipid regulating agents or sex hormones of instant dependent claims. GB also fails to teach that the active agent is partly dissolved or suspended. However, GB teaches the same vehicles that are also described in the instant examples and specification, and accordingly, absent showing evidence to the contrary, it is examiner's position that the active agent prepared by the process of GB results in partially suspended and partially dissolved formulation.

With respect to the amounts of active agent, optimizing the amount of the active agent in the formulation of GB or Nagahama, with an expectation to obtain a thermodynamically stable microemulsion that does not coalesce would have been within the scope of a skilled artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM Monday-Friday, except alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
January 6, 2005